

Inventor(s): BOUCHARD *et al.*  
Application No.: 10/661,780  
Attorney Docket No.: 098501-0305998

### III. REMARKS

#### **Preliminary Remarks**

Reconsideration and allowance of the present application based on the following remarks are respectfully requested. Claims 22, 26-34, and 36-42 are currently pending and remain at issue in this application. This response is timely filed.

On pages 2 and 3 of the official action, the examiner objected to the word "administrating" in claim 39. The applicants have amended claim 39 correcting the typographical error of the word administering. The applicants have also amended claims 28-34, 36-38, and 40-42 to insert a comma before the "wherein" clause and not for any reasons related to patentability. The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

#### **Patentability Remarks**

##### ***Rejection Pursuant to 35 U.S.C. §112, Second Paragraph***

On page 3 of the official action, the examiner rejected claims 22, 26-34, and 36-38 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Specifically, the examiner alleged that the phrase "the improvement" in claim 22 lacked antecedent basis. The examiner asserted that if claim 22 is to be a Jepson claim, the proper Jepson claim format should be used. The examiner also asserted that the word "clomphencitratc" lacks proper antecedent basis in claim 26.

Amended claim 22 is now directed to a method of treating fertility disorders by administering an LHRH-antagonist selected from the group consisting of ganirelix, antarelix antide, azaline B, ramorelix, A-76154, Nal-Glu, 88-88 and cetrorelix, and inducing follicle growth by administration of hMG or recombinant FSH (Controlled Ovarian Stimulation) in combination with clomiphene, wherein the administration of said LHRH-antagonist is sufficient to suppress endogenous LH while maintaining FSH secretion at a natural level and estrogen development is not affected until ovulation induction. The applicants respectfully submit that the limitation "the improvement" has been removed from the language of claim 22 and replaced with a "wherein" clause to further characterized the administration of LHRH-antagonists. Accordingly, the language of amended method claim 22 is not in a

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Jepson claim format and contains proper antecedent basis for all terms and steps of the claim method.

The applicants further submit proper antecedent basis exists for dependent claim 26 with regard to the terms clomiphene. Specifically, the term "clomiphene" is present in independent claim 22 from which claim 26 draws its dependency. In view of the foregoing amendment and remarks, the applicants respectfully request that the rejection of claims 22, 23, 26, 27, 29-32, 35, 37, 38, and 40 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite, has been overcome and should be withdrawn.

***Rejection Pursuant to the Judicially Created Doctrine of Obviousness-Type Double Patenting***

On page 4 of the official action, the examiner rejected claims 22, 26-34, and 36-42 as allegedly being obvious over claims 1-6 of U.S. Patent No. 6,319,192 (hereafter the "'192 patent") under the doctrine of non-statutory obviousness-type double patenting. Specifically, the examiner asserted that claims 1-6 of the '192 patent recite a method of therapeutic management of infertility comprising administering an LHRH-antagonist, stimulating ovarian follicle growth, inducing ovulation with HCG, native LHRH, LHRH agonist or recombinant LH, and inseminating by sperm injection, wherein the LHRH antagonist administered may be cetrorelix or antarelix and ovarian follicle stimulation is achieved by administration of anti-estrogens. The examiner concluded that since the claims of the '192 patent administer LHRH antagonists so that endogenous LH is suppressed, the maintenance of FSH secretion at a natural level would be inherent regarding normal estrogen development.

Solely to expedite prosecution and place the pending claims in a condition for allowance, the applicants hereby submit a terminal disclaimer stating that U.S. Patent No. 6,319,192 and the instant application are commonly owned and the claims are a result of a joint research agreement. In view of the foregoing remarks, the applicants respectfully submit that the rejection of claims 22, 26-34, and 36-38 under the judicially created doctrine of obviousness-type double patenting in view of the '192 patent has been overcome and should be withdrawn.

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### III. CONCLUSION

In view of the foregoing, the applicants believe that the claims are in form for allowance, and hereby respectfully solicit such action. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, the examiner is strongly urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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